PB81-241481

Chemical Selection Methods
An Annotated Bibliography

Tracor Jitco, Inc.
Rockville, MD

Prepared for

Environmental Protection Agency
Washington, DC

Nov 80

U.S. Department of Commerce
National Technical Information Service
NTIS

PB81-241481

United States
Environmental Protection
Agency

Office of Pesticides
and Toxic Substances
Washington DC 20460

EPA 560/7118-80-001
November 1980

Toxic Substances

EPA

Chemical Selection Methods: An Annotated Bibliography

Toxic Integration Information Series

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NATIONAL TECHNICAL
INFORMATION SERVICE
U.S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA 22161

30272-101

REPORT DOCUMENTATION PAGE	1. REPORT NO. EPA 560/TIIS-80-001	2.	3. Recipient's Accession No.
4. Title and Subtitle: Chemical Selection Methods: An Annotated Bibliography. Toxics Integration Information Series			5. Report Date: November 1980 date of publication 6.
7. Author(s): John N. Gevertz (EPA/OTI), Judy Hoffman (Tracor Jitco), and Elaine Bild (EPA/OTI)			8. Performing Organization Rept. No.
9. Performing Organization Name and Address: Tracor Jitco, Inc. 1776 East Jefferson Street Rockville, MD 20852			10. Project/Task/Work Unit No.: Technical Directive 25 11. Contract(C) or Grant(G) No. (C) 68-01-6021 (G)
12. Sponsoring Organization Name and Address: U. S. Environmental Protection Agency 401 M Street, S.W. Washington, D.C. 20460			13. Type of Report & Period Covered: Final 14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

Regulatory agencies charged with control of toxic chemicals have examined and are examining various methods to select chemicals of concern from the universe of chemical substances. Chemical selection refers to such activities as priority setting, ranking, indexing, and sorting. These efforts have included the development of various systematic selection methods such as scoring systems. This annotated bibliography is intended to provide interested individuals with a variety of methods for chemical selection.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement: Release unlimited	19. Security Class (This Report): Unclassified	21. No. of Pages
	20. Security Class (This Page): Unclassified	22. Price

(See ANSI-Z39.18) See Instructions on Reverse

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)
Department of Commerce

Toxics Integration Information Series

EPA 560/TIIS-80-001
November 1980

Chemical Selection Methods: An Annotated Bibliography

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Office of Toxics Integration
with the assistance of
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FOREWORD

The selection, ordering, and ranking of chemical substances stands as one of the most critical, yet difficult, tasks facing those who are engaged in the testing, assessment, and regulation of substances as well as enforcement of those regulations. In the course of our studies of decision-making processes in the Office of Toxics Integration, we have discovered a number of resource materials that might serve the needs of those in other Federal agencies as well as those in States, industry and academia. This annotated bibliography is intended to assist those faced with decisions related to the selection of chemicals to become aware of the state-of-the-art for those decision-making processes. Hopefully, duplicative and overlapping efforts can be avoided through such awareness.

It is anticipated that this bibliography will be updated and expanded. Your comments, suggested revisions, and additions should be addressed to: Office of Toxics Integration, TS-777, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, telephone (202) 755-2778. Copies of all materials referenced in this bibliography are available for examination in the Headquarters' EPA Library, room M2404 Waterside Mall, 401 M Street, SW, Washington, DC.

Walter W. Kovalick, Jr.
Director
Integration Staff

Acknowledgements

This bibliography was prepared by the Environmental Protection Agency's Office of Pesticides and Toxic Substances (OPTS). Document identification and retrieval, as well as preparation of original abstracts, was conducted primarily by Tracor-Jitco, Incorporated, under contract to the Management Support Division of OPTS. Ginny Shreve of Tracor-Jitco was principally involved in the effort; Doug Sellers of the Management Support Division was Project Officer. John Gevertz of the Office of Toxics Integration served as Technical Monitor.

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INTRODUCTION

This bibliography is intended to provide individuals interested in chemical selection (priority setting, ranking, indexing, sorting) with a collection of relevant materials. Examination of such materials may prevent unnecessary duplication of effort and aid in the development of new useful methods to assist in selecting chemicals of concern. The selection methodologies listed here were developed by EPA, other Federal agencies, State agencies and contractors for these agencies, as well as industrial, academic and public interest organizations.

Included with each entry is a brief abstract. Some of the abstracts were prepared specifically for this effort; others accompanied the original documents.

Chemical selection has been and continues to be of interest to many groups concerned with the regulation of toxic substances. For example, the Toxic Substances Control Act (Public Law 94-469) requires the Environmental Protection Agency to compile an inventory of chemical substances manufactured, imported, or processed in the United States for commercial purposes.[1] By June 1980, over 55,000 chemicals were included in this Inventory. EPA is also responsible for determining which of these chemicals may require testing, which should be subject to information gathering rules, and which might require regulatory controls. Making these types of determinations requires "selecting" small groups of substances from larger groups.

Because of the large number of potentially toxic substances and the variety of actions possible under numerous Federal and State authorities, development and use of systematic selection methodologies has become a necessity. Of course, use of systematic selection methods is appropriate only at certain stages in any regulatory decision process. For example, early in any process, candidates must be screened to identify substances clearly requiring some assessment; later, candidates from the first group must be chosen for more in-depth consideration; and finally, a few candidates are selected for regulation. Thus, selection methods can be applied to candidate pools that are large or small and to information ranging from limited to extensive. However, selection schemes must be developed and employed "operationally"; that is, with regard to the requirements of the particular stage in the regulatory process that is being considered.

There are also some inherent limitations in the use of any chemical selection methodology. Most selection methods involve consideration of some or all of the following factors: carcinogenicity, mutagenicity, teratogenicity, neurotoxicity, and other chronic human health effects; acute human health effects; environmental toxicity; types and quantities of emissions, human and environmental exposure; bioaccumulation; costs of regulations; and regulatory

[1] Excluded from this inventory are mixtures, pesticides, tobacco, food, food additives, drugs, cosmetics, firearms, and nuclear materials.

authority. Any method which involves combining various categories of information to arrive at some single index of concern runs the risk of rendering the original data meaningless.

Existing systematic selection methods generally utilize some form of scoring or ranking which involves assigning a dimensionless or arbitrary number to each of the factors being considered. Conversions of this type tend to obscure the original data, and fail to incorporate a measure of uncertainty. Suppose, for example, that the number "3" is assigned to any substances to which between 10,000 and 100,000 persons are exposed. Not only will this number fail to convey accurately the number exposed, it will also fail to provide an indication of the level of uncertainty in the estimate or an indication of the basis for the estimate (e.g., monitoring, modeling).

Another limitation to the use of many scoring methods is that they employ simple additive or multiplicative algorithms to combine factors. Such algorithms often ignore or distort the true relationship between factors. In the case of an additive system, for example, suppose that for Chemical X, carcinogenicity is assigned a "5", no information is available for six other factors so each is assigned a "0", and persistence is assigned a "3". The total score for Chemical X is "8". For Chemical Y, carcinogenicity is assigned a "1", each of six other factors is also assigned a "1", and persistence given a "3". The total score for Chemical Y is, thus, "10". It is unclear, however, whether Chemical Y is really more hazardous than Chemical X, regardless of the policy framework governing the evaluator.

Some methods utilize "flagging" or "triggering," as a means of selection. "Flagging" refers to setting threshold levels or employing "discriminators" for various factors in order to select candidates. Any chemical may be "flagged" if it exceeds a discriminator for a single factor or, to allow for synergism, if it exceeds the discriminators for certain combinations of factors. The use of "flags" or "triggers" in a selection scheme avoids the complex data manipulations required for the systems discussed above. However, selection methodologies using "flagging" are only effective if the factors are chosen in a careful logical manner.

Systematic selection methodologies will certainly become significant in the selection of chemicals for assessment and regulation. Such methods provide consistency in decision making. They also promote efficient resource allocation. Finally, use of these methodologies will aid in the defensibility and effectiveness of regulatory actions.

This bibliography should assist individuals in identifying previous efforts relevant to their needs, and foster an understanding of the nature of selection methods. Several different types of systematic selection processes are included in this work. Those listed were chosen specifically because they are relevant to sorting groups of chemicals. Before employing any of these systems or developing new methods, however, the potential limitations of each should be understood.

Chemical Selection Methods

Allport, J.; Casey, S.; Cook, J.; et al.
Stanford Research Institute, Menlo Park, California
A Study of Industrial Data on Candidate Chemicals for Testing-Final Report
Prepared for U.S. Environmental Protection Agency
Office of Toxic Substances
EPA-560/5-77/006, 1977, Research Request No. 1
NTIS #PB-274 264/1GA

This report summarizes the work done by Stanford Research Institute for EPA's Office of Toxic Substances and includes three major parts. (1) Data previously collected on an NSF study was supplemented to provide the following information where available on 667 industrial chemicals: (a) United States production; (b) estimates of quantities released annually to the environment; (c) major uses; and (d) references on mutagenicity tests. Mutagenicity data on 25 chemicals were evaluated after developing a list of assays and criteria for classifying the results as either positive or negative/inadequate. (2) Tables which contain economic information on 1791 chemicals belonging to 26 structural classes considered to represent potential industrial carcinogens and mutagens were prepared. For those chemicals with annual production greater than one million pounds, market forecasts which present a brief summary of production, consumption patterns, major uses, possible substitutes, and growth trends were prepared. (3) Carcinogenicity data for all chemicals belonging to three classes (epoxides, alkyl halides, and vinyl halides) were used to correlate structural features with carcinogenic activity. Criteria were developed for estimating the potential carcinogenicity of chemicals in each class. These criteria were applied to those chemicals in each class known to be produced commercially or for which there was evidence of significant human exposure. The results of the study were summarized in three separate reports.

Archer, S.R.; McCurley, W.R.; Rawlings, G.D.
Monsanto Research Corporation, Dayton, Ohio
Source Assessment: Pesticide Manufacturing Air Emissions--Overview and Prioritization
Prepared for U.S. Environmental Protection Agency
Industrial Environmental Research Lab
Research Triangle Park, North Carolina
EPA-600/2-78/004d, March 1978
NTIS #PB 279-171/3ST

The report is an overview of the pesticide manufacturing industry and ranks 80 major pesticides based on their potential environmental burden from an air pollution standpoint. Production of synthetic organic pesticides was about 640,000 metric tons in 1974. Thirty-seven major synthetic organic pesticides, those with annual production of 4540 or more tons, accounted for 74% of the market. Elemental chlorine is common to most pesticides, but other raw materials include hydrogen cyanide, carbon disulfide, phosgene, phosphorus pentasulfide, hexachlorocyclopentadiene, various amines, and concentrated acids and caustics. Air pollution aspects of the pesticide manufacturing industry are essentially without quantitatve data. For some plants, the pollution caused by loss of active ingredients is less significant than that caused by unreacted by-products. Evaporation from holding ponds and evaporation lagoons may also be an emission source, although few quantitative data are available. Emissions emanate from various pieces of equipment and enter the atmosphere as both active ingredients and as raw materials, intermediates, and by-products. Air emission control devices include baghouses, cyclone separators, electrostatic precipitators, incinerators, and gas scrubbers. Synthetic organic pesticide production in 1985 will be about 806,000 metric tons.

Astill, B.D.; Lockhart, H.B., Jr.; Moses, J.B.; et al.
Eastman Kodak Company, Rochester, New York
Sequential Testing for Chemical Risk Assessment
Presented at the Second International Congress on Toxicology
Brussels, Belgium, July 6-11, 1980

A method of quantitatively evaluating environmental and health hazard is presented. Four categories of effects were established: the magnitude of environmental exposure (ME), the magnitude of human exposure (MH), the effects on human health of an exposure (H), and the effects on the environment of an exposure (E). The criteria for MH are production per year, number of people exposed, duration of exposure, and number of groups exposed. The criteria for ME are amount discharged per year, number of discharge sites, number of discharges per year, and half-life in the environment. Criteria for H are the oral median lethal dose in rats, reversibility of immediate effects, and reversibility of prolonged effects. Criteria for E are the 5 hour median inhibitory concentration on waste water treatment microorganisms, the median lethal concentration on fish, and the octanol-water partition coefficient as a measure of bioconcentration potential. Each criterion is given a maximum, median and minimum range and these are ranked 1, 2, or 3, respectively. The cumulative health or environmental score for a compound is evaluated so that scores of 9 or less, 10 to 13, 14 to 17, or 18 or more suggest testing levels I, II, III, or IV, respectively. Level I testing includes physical and chemical properties, acute health effects, in vitro mutagenesis and acute environmental tests. Level II includes 2 week feeding or inhalation tests, skin painting tests, more mutagenesis tests, activated sludge effects, photodegradation, biodegradation, effects on plant growth and germination and partition coefficients. Level III includes 90 day feeding or inhalation, fertility tests, teratology, half-life and metabolites in rodents, nitrification inhibition, algal toxicity, 14 to 21 day biodegradation, simulated fate study, larval fish studies, and bioconcentration factor. Level IV includes 2 year feeding studies, 3 generation reproduction studies, teratology, pharmacokinetics, biodegradation products, soil interaction, and long term aquatic studies. If testing is conducted the results may then be entered into the scoring and the total score reassessed. The authors conclude this screening protocol is both cost and time effective. Over five hundred chemicals have been tested over two years.

Becker, D.S.
IIT Research Institute
Design of a Chemical Hazard Ranking System-Final Report
Prepared for U.S. Consumer Product Safety Commission
Bethesda, Maryland
Contract No. CPSC-C-77-0068
December 27, 1978

The Consumer Product Safety Commission would like to rank the health hazards of the chemicals in consumer products to enable them to allocate their resources in an appropriate manner. The three main factors of consumer chemical hazard due to consumer products are: toxicity, dose per person and population exposed. Unfortunately, these factors are not available as standardized statisitics, nor can they be calculated by standardized formulas. Population exposed could be computed from marketing data for each product, but this would be prohibitively expensive. Dose per person should be computable from a product's known characteristics (aerosol, skin contact, frequency of use, etc.), though accepted standardized equations do not exist. Chemical toxic strength factors for carcinogens, mutagens and teratogens are known for only a few percent of consumer chemicals. No standard method for extrapolating latent toxic strength factors from data on the tested chemicals to the untested ones exists. Typically, these problems have been overcome by having panels of experts rate the 3 factors based on unstated rules. However, the scope of the problem for consumer chemicals favors a computerized approach based on systematic procedures. First, such a system could efficiently re-rank all chemicals as new data became available. Second, it is less expensive to use automated procedures for this application. Third, it is more precise to make all the decision criteria explicit. This report presents uniform techniques for estimating the toxicity, dose per person and population exposed factors and for calculating a hazard score from them. The procedures are sufficiently general that they can be applied to all consumer chemicals within an automated system using available data.

Branson, D.R.
Hazard Assessment of Chemicals in the Aquatic Environment
Presented at the 18th Annual Meeting of the Society of Toxicology, New Orleans, March 13, 1979

A method is presented for selecting priority pollutants based on the principles of hazard assessment for chemicals in the aquatic environment. The method combines environmental release rates, ambient levels in fish and water, persistance and bioaccumulation, chronic toxicity to aquatic organisms, and acceptable daily intake levels by humans. A case study illustrates the method using two chemicals with fairly high environmental release rates, di-2-ethylhexylphthalate and linear alkylbenzene sulphonate, and two chemicals with moderately high release rates, polychlorinated biphenyl and pentachlorophenol.

Brown, S.L.
Stanford Research Institute, Menlo Park, California
Setting Priorities for Environmental R and D on Army Chemicals
Annual Report for 1976
Prepared for Army Medical Research and Development Command
Contract No. DAMD17-75-C-5071
NTIS #AD-A046 357/0ST, January 1977

The Environmental Protection Research Division of the Army Medical Research and Development Command is charged with recommending criteria for environmental standards dealing with the manufacture, use, and disposal of chemicals in Army activities. This report presents a methodology that can assist the Army in allocating resources among candidate research and development studies on the environmental effects of Army chemicals. The basis of the methodology is a mathematical model of the process leading from the initial pollution of air, water, or land to the eventual environmental effects of the chemicals in question. The model estimates a total hazard value, weighted among human and ecological effects, with a corresponding uncertainty due to lack of knowledge. The allocation methodology then compares the reduction in hazard uncertainty expected to be achieved after a research study with the cost of the study. Candidate studies are ranked according to this ratio.

Brown, S.L.; Chan, F.Y.; Jones, J.L., et al.
Stanford Research Institute, Menlo Park, California
Research Program on Hazard Priority Ranking of Manufactured Chemicals
5 volumes
Prepared for National Science Foundation
Washington, D.C.
NTIS #PB-263 161/2ST; #PB-263 162/0ST; #PB-263 163/8ST; #PB263 164/6ST; #PB263 165/3ST, April 1975

The research effort by SRI was divided into two phases. In Phase I, the universe of manufactured organic chemicals was reduced to 250 chemicals according to the highest calculated values for the release rates for these chemicals. Data on relevant physical and chemical properties for these chemicals were presented to the Advisory Panel during its meeting in Menlo Park, California, on August 26-27, 1974. From this list of 250 chemicals and from a list of 41 chemicals designated by the Advisory Panel as 'Most Wanted Chemicals', the members of the Advisory Panel selected 80 chemicals for Phase II study, as the chemicals with the greatest potential for environmental effects. In Phase II of this two-phase effort, 80 chemicals having the greatest potential for environmental effects were studied. Information was collected on the extent of the environmental exposure to these chemicals (during manufacture and use) and on the possible environmental effects of this exposure (chemical, physical, and biological properties, persistence, and toxicity). A questionnaire survey of industry was conducted to determine the amount and types of losses in the manufacturing plants. Information from this survey is tabulated. The following summary reports are submitted for each of the 80 chemicals: (1) A flow diagram showing industrial data on the amounts used for various applications; (2) a one-page assessment of the data gathered on toxicology and environmental persistence; (3) a computer printout of a tabular summary of the important data gathered; and (4) copies of the 25 most pertinent abstracts found in the area of toxicology. The report is divided into five volumes.

The first volume contains chemicals 1-20: Tetrakis(hydroxymethyl)phosphonium chloride, Benzo(a)pyrene (BAP), Tetraethyl lead, Vinyl chloride, Hexachlorobenzene, o-Cresol, Ethylbenzene, Nonylphenol, ethoxylated (9 moles of ethylene oxide), Hexachlorobutadiene, Vinylidene chloride, Toluene, Ethylene dibromide, Tris(2,3-dibromopropyl) phosphate, Ethylene dichloride, Trichloroethylene, 1,1,1,-Trichloroethane, Carbon tetrachloride, Chlorinated paraffins (35-64% chlorine), Perchloroethylene, Dichlorodifluoromethane.

The second volume contains chemicals 21-40: Benzene (chemical uses), Silicone fluids, Nitrobenzene, Toluenediisocyanate (TDI), Xylenes - mixed total, Aniline, Dimethyl terephthalate, Trichlorofluoromethane, p-Dichlorobenzene, Tetrabromoethane, Methylenebis(2-chloroaniline), Polyhalogenated biphenyls (Aroclor 1254), Tricresyl phosphate, Fluorescent brightening agents (no. 28), Polyvinyl chloride, Methylene chloride, Dichloropropene, Dichloropropane mixture, and Ethyl chloride.

The third volume contains chemicals 41-60: (Ethylenedinitrilo)tetraacetic acid, tetrasodium salt, Benzidine, Zinc di(butylhexyl) phosphorodithioate, N-(Dimethylpentyl)-N-phenyl-p-phenylenediamine, Vinyltoluene, Methyl bromide, Mercaptobenzothiazole, Chloroform, Acetontrile, Di(ethylhexyl) phthalate, Vat Blue Dye no. 6 (Dichloroindanthrone), Di(ethylhexyl) adipate, Dimethylamine, Dichlorobenzidine, Hexamethylenetetramine, Acyclic xanthic acid salts (Sodium isopropylxanthate-Dow Z-11), Sulfolane-p-Nonylphenyl manganese phosphite, Nitrilotriacetic acid (trisodium salt), and Diarylarylenediamines (mixed) (Wingstay 100).

The fourth volume contains chemicals 61-79: Polyacrylonitrile (fibers), Naphthalene, N,N-Dimethyldodecylamine oxide, Chloroprene, Formaldehyde (37% by weight), Bis(hydrogenated tallow alkyl) dimethylammonium chloride, Methyl chloride, Dioxane, Ethylene oxide, Allyl chloride, Ethylenimine, Phenol, Tri(chloroethyl)phosphate, Polyethylene glycols (MW 400), Methoxyethanol, Dodecylbenzenesulfonic acid(sodium salt), Bis(chloroethyl) ether, Dodecyl mercaptan, Polyurethane and diisocyanate resins, and Ethylene.

The fifth volume contains a listing of the references for the data collected and general notes describing the data.

Brown, S.L.; Holt, B.R.; McCaleb, K.E.
Stanford Research Institute, Menlo Park, California
Systems for Rapid Ranking of Environmental Pollutants: Selection of Subjects for Scientific and Technical Assessment Reports
Prepared for U.S. Environmental Protection Agency
Office of Research and Development
Office of Health and Ecological Effects
Washington, D.C.
EPA-600/5-78/012, June 1978
NTIS #PB-284-338/1ST

This document reports the results of the development and testing of a system for rapidly ranking environmental pollutants. One potential use for the system is in choosing the most important candidates for Scientific and Technical Assessment Reports (STAR). Of several possible approaches to ranking environmental agents, a system depending on expert opinion but assisted by an objective subsystem was selected for development. The system defines procedures for collecting, processing, and evaluating data on production and use; environmental transport, transformation, and rate; and human health and welfare and ecological effects. A test of the objective subsystem confirmed the utility of the system. Of ten candidate agents, the three highest ranked were cyanides, carbon disulfide, and beryllium.

Carins, J.; Dickson, K.L., Maki, A.W.
Estimating the Hazard of Chemical Substances to Aquatic Life
Hydrobiologia, 64(2):157-66 (1979)

A conceptual framework for conducting a hazard assessment is presented. Various toxicity tests and procedures for evaluating hazards to aquatic life are compared, and the decision criteria used in these procedures are discussed. The use of safety factors or "uncertainty factors" is discussed as a central concept in a sequential testing approach in which estimates of expected chemical concentrations in the environment and their effects can be made with an increasing degree of accuracy. The state of the art of assessing hazards from chemicals to aquatic life is reviewed; safety, hazard, and risk concepts involved in such assessments also are discussed. Particular attention is given to hazard assessment procedures developed by the American Society for Testing Materials, American Institute of Biological Sciences, and Monsanto.

Cleland, J.G.; Kingsbury, G.L.; Sims, R.C.; White, J.B.
Research Triangle Institute
Research Triangle Park, North Carolina
Multimedia Environmental Goals for Environmental Assessment. 4 Volumes
Prepared for U.S. Environmental Protection Agency
Industrial Environmental Research Laboratory
Research Triangle Park, North Carolina
EPA-600/7-77/136a, EPA600/7-77/136b, November, 1977, EPA600/7-79/176A, EPA600/7-79/176B, August, 1979
NTIS #PB-276 919/8ST, #PB276 920/6ST, #PB-115108, #PB80-115116

The report gives results of a study of the derivation of Multimedia Environmental Goals (MEG's). MEG's are levels of significant contaminants or degradents (in ambient air, water, or land, or in emissions or effluents conveyed to the ambient media) that are judged to be: appropriate for preventing certain ne ative effects in the surrounding populations or ecosystems; or representative of the control limits achievable through technology. In the context of deriving MEG's, Volume I: offers perspective on the broad range of contaminants whose control is vital to both industry and the public; further develops and defines indicators designating contaminants which must be given priority consideration for immediate control and for subsequent research; brings existing and emerging data together for use in environmental assessment; and explores some basic methodologies which provide the present MEG's, and which also suggest directions for refined methodologies. MEG's are projected for more than 650 pollutants. Of these, 216 receive full attention in Volume II. MEG charts along with the Background Information Summaries for these substances are presented in this volume which includes 162 organic and 54 inorganic substances. Volumes III and IV address 586 organic compounds. Volume III includes the following categories:
Aliphatic Hydrocarbons; Alkyl Halides, Ethers; Halogenated Ethers and Epoxides; Alcohols, Glycols, Epoxides; Aldehydes, Ketones; Carboxylic Acids and Derivatives; Nitriles; Amines; Azo Compounds, Hydrazine Derivatives; Nitrosamines. Volume IV includes the following categories:
Thiols, Sulfides, Disulfides, Sulfonic Acids, Sulfoxides; Benzene, Substituted Benzene Hydrocarbons; Halogenated Aromatic Compounds; Aromatic Nitro Compounds; Phenols; Halogenated Phenolic Compounds; Nitrophenols; Fused Polycyclic Hydrocarbons; Fused Non-alternant Polycyclic Hydrocarbons; Heterocyclic Nitrogen Compounds; Heterocyclic Oxygen Compounds; Heterocyclic Sulfur Compounds; Organophosphorus Compounds.

Cramer, G.M.; Ford, R.A.; Hall, R.L.
Estimation of Toxic Hazard - A Decision Tree Approach
Food Cosmet. Toxicol., 16(3):255-76 (1978)

A procedure using 33 criteria for establishing toxic hazard is presented as a decision tree organized into branches dealing with major chemical classifications and intended for use with all ingested, structurally defined organic and metallo-organic substances. The criteria are based on features of chemical structure, occurrence in body tissues and fluids, and natural occurrence in food. The logic of the tree rests heavily on known data on metabolism and toxicity. The classification according to presumptive toxicity can be combined with knowledge of human intake to provide a protection index for each substance. The index can be used to establish priorities and define tentatively the extent of appropriate testing. It is noted that the procedure has been applied to a large number of pesticides, drugs, food additives, and industrial and environmental chemicals of known biological properties. Because the procedure has not yet resulted in any underestimation of toxicity, it is seen as a practical means for discriminating effectively among different levels of probable hazard.

Dorsey, J.A.; Johnson, L.D.; Statnick, R.M.; et al.
Environmental Assessment Sampling and Analysis: Phased Approach and Techniques for Level 1
Prepared for U.S Environmental Protection Agency
Industrial Environmental Research Laboratory
Research Triangle Park, North Carolina
EPA-600/2-77/115, June 1977
NTIS #PB-268 563/4ST

The report discusses a three-level approach to sampling and analysis for environmental source assessment. A research program was initiated to develop a sampling and analytical approach for conducting environmental source assessments of the feed, product, and waste streams associated with industrial and energy processes. An environmental source assessment identifies potential air, water, and terrestrial problems for both regulated and unregulated pollutants. The three-level sampling and analysis approach resulted from this program. Level 1 is a complete survey of all streams, using simplified, generalized sampling and analytical methods which permit priority ranking; i.e., hazardous streams are distinguished from those less hazardous or relatively innocuous in nature. Level 2 is detailed sampling and analysis of the streams ranked in the highest priority by the Level 1 survey. Other streams may then be addressed according to potential hazard. Level 3 involves continuous monitoring of 'key' indicator materials to evaluate the effect on emissions of process variability.

Enviro Control Inc.
Rockville, Maryland
Scoring Chemicals for Health and Ecological Effects Testing
Proceedings of TSCA-ITC Chemical Scoring System Workshop, February 25-28, 1979

Since its inception in early 1977 the TSCA-Interagency Testing Committee has submitted to the EPA Administrator four reports recommending a total of 33 chemicals and chemical categories to be tested for their potential to cause unreasonable risk to human health or the environment. In order to identify these chemicals from among the approximately 44,000 chemicals in commercial production in the United States today it was essential for the Committee to have procedures for ranking chemicals as to the need for testing to deterine their hazard to human health and the environment.

The Committee used existing source lists of hazardous chemicals to form a Master File, as described in the Committee's Initial Report to the Administrator. This list of 1,700 chemicals was subjected to scoring, first on the basis of production, release, operation, and exposure, and subsequently on the basis of biological activity. The scoring procedure was developed in conjunction with Clement Associates, Inc., the ITC's support contractor during its first two years of operation, and is described in this report.

In an effort to make any possible improvement in this numerical scoring system the ITC decided to subject the scoring system to the scrutiny and criticism of individuals from academia, industry, and government who are expert in the various aspects of release, exposure, and effects that make up the system. Enviro Control, Inc. was awarded a contract to organize a scoring workshop and to prepare a report on the proceedings. The workshop was held in San Antonio, Texas, February 25-28, 1979, with approximately 80 technical experts participating.

Fiksel, J.; Segal, M.
Arthur D. Little, Inc.
An Approach to Prioritization of Environmental Pollutants: The Action Alert System
Prepared for U.S. Environmental Protection Agency
Office of Water Regulations and Standards
Monitoring and Data Support Division
Washington, D.C.
Contract No. 68-01-3857
Final Draft, June 1980

The Action Alert System was developed to assist the Office of Water Regulations and Standards in evaluating available data, setting priorities, and determining appropriate actions. The system can aid in sorting large groups of chemicals into "manageable clusters" for further examination.

Required data elements are concentrations - including drinking water, human diet, and ambient water - and effects data - including chronic mammalian, acute human or mammalian, and aquatic toxicity. Six auxiliary modules have been developed to serve as surrogates in some cases where data are lacking or to enable use of more extensive data where it exists. This report includes a detailed description of the conceptual development of the system, a presentation of the six auxiliary modules, and a user's guide. The user's guide provides detailed instructions for the application of the action alert system to the ranking of specific chemicals.

Flinn, J.E.; Thomas, T.J.; Bishop, M.D.
Battelle Columbus Laboratories
Columbus, Ohio
Identification Systems for Selecting Chemicals or Chemical Classes as Candidates for Evaluation
Prepared for U.S. Environmental Protection Agency
Office of Toxic Substances
EPA-560/1-74/001
NTIS #PB-238 196/OGA, November 1974

This report is a review of various systems for selecting, assessing, and ranking chemicals for their health and environmental effects. Systems for two general areas are considered: health planning, including environmental, occupational, and general health; and environmental management. It is noted that the term "system" is broadly defined to include not only formalized organizational structures, models, and methodologies, but also less formal tools, methods, and working groups which have been created to rank chemical substances or effects. Existing systems are classified in several ways. Some are considered information repositories for chemical data, particularly toxicity data. Other systems are classified with respect to whether their function is to identify chemical substances before or after general exposure of the public and the environment occurs. Each of these types is further categorized into those which identify new or unrecognized chemical "stressors" and those which evaluate recognized "stressors". Particular attention is given to methods used by various Federal agencies. It is concluded that most existing systems are deficient in that they (1) focus on acute rather than long-term effects; (2) have a limited domain of concern; and (3) are not designed to identify hazards from degradation products, synergistic effects, or effects on the nonliving environment. An appendix summarizes results of a seminar on "Early Warning Systems for Toxic Substances" held January 30 - February 1, 1974.

Fuller, B.; Hushon, J.; Kornreich, M.; et al.
Mitre Corporation, McLean, Virginia
Preliminary Scoring of Selected Organic Air Pollutants, 5 Volumes
Prepared for U.S. Environmental Protection Agency
Office of Air Quality Planning and Standards
Research Triangle Park, North Carolina
EPA-450/3-77/008a,b,c,d,e, October 1976
NTIS #PB-264 442/5ST

This report presents a scheme for evaluating the relative hazard to humans resulting from air emissions during production of synthetic organic chemicals. Data on production, fraction lost during production, volatility, and toxicity have been compiled for 637 organic chemicals. A scoring system using these data elements was developed and is described in this report. Scores assigned to the 637 chemicals are presented. Four appendices were published with this report. The appendices are dossiers containing chemistry, production, and toxicity data for the 637 synthetic organic chemicals.

Jones, C.J.
The Ranking of Hazardous Materials by Means of Hazard Indices
J. Hazard. Mater., 2:363-89 (1977-78)

Several indexing models for use in landfill management, transport of dangerous goods, environmental quality assessment, and other areas are reviewed. Suggestions are then presented for developing a hazard index for evaluating waste management options. The procedure involves listing the materials or wastes of interest and the management or disposal options to be considered. The properties of the materials or wastes which are relevant to the evaluation process are obtained from the existing literature or from laboratory measurements. A combination model appropriate to the management situation must then be constructed. The author recommends the additive utility model, but notes that other models may be more appropriate in certain cases. The normalized indexes for each material and the relative utility range for each property are derived from the data and the overall index is calculated using the combination model. The overall indexes must reflect the actual properties of the material in combination with the relative importance attributed to each property by the weighting factor. The author observes that if the combination model is mathematically sound, the use of an indexing and combination model allows versatility in quantifying value judgements about aspects of a given material's environmental behavior.

Keith, L.H.; Telliard, W.A.
Priority Pollutants. I. A Perspective View
Environ. Sci. Technol., 13(4):416-23 (1979)

The historical origins of the Environmental Protection Agency's (EPA) Priority Pollutants and the development of the Priority (Water) Pollutants Protocol are related. Events are traced beginning with the court decision in 1978 that resulted in adoption of the EPA Consent Decree to control the levels of pollutants in industrial wastewater discharges. Components of the decree are reviewed, including formation of the Toxic Pollutant List to aid in the classification of harmful substances. It is noted that since the decree lacked allowance for time in solving analytical problems in testing for these substances in wastewaters, the EPA adopted four criteria to prioritize and select representative compounds from each group. First, all compounds specifically named on the Toxic Pollutant List were automatically included. (The availability of chemical standards for verification and quantification was considered mandatory). Second, compounds not found on the list should be tested if they accounted for five percent or more of the total known listing for the class of compounds. Third, all chemical production data should be reviewed where available. Fourth, other sources were examined to determine if the compound was a recognized water pollutant. Next, the screening, verification, and monitoring strategy developed by EPA for testing water for pollutants is presented. Unresolved problems in the screening stage are discussed, along with automated software programs being adopted to speed up the analysis process. Future plans and first drafts for implementation of the monitoring phase are considered, and a list of the 129 compounds on the Toxic Pollutant List is included.

Kimerle, R.A.; Gledhill, W.E.; Levinskas, G.J.
Monsanto Co., Environmental Assessment Department, St. Louis, Missouri
Environmental Safety Assessment of New Materials
In: Cairns, J.; Dickson, K.L.; Maki, A.W.; Eds.
American Society for Testing Materials STP No. 657:132-146 (1978)

A procedure is presented for evaluating the hazard to aquatic organisms of new materials prior to their commercialization. The procedure uses environmental fate and aquatic organism toxicity data in the sequential phases of screening, predicting, confirming, and monitoring to reach a decision either to continue the toxicity testing, terminate the project because of unacceptable risk, or cease testing because of an acceptable risk. The screening phase involves short term acute tests, while the predictive phase involves short and long term laboratory studies. In the confirmation phase, environmental field studies are designed to answer critical questions of enviromentfal safety. In the monitoring phase, field studies under actual use conditions after commercialization are conducted to confirm the ultimate safety of the material. The types of tests in each phase and the criteria which determine which specific tests are needed are presented. The criteria for evaluating whether or not a hazard exists also are discussed.

Margler, L.W.; Rogozen, M.B.; Ziskind, R.A.; et al.
Science Applications, Incorporated, Los Angeles, California
Rapid Screening and Identification of Airborne Carcinogens of Greatest Concern in California
J. Air Pollut. Control Assoc., 29(11):1153-7 (1979)

The method used by the California Air Resources Board to identify quickly and rank potentially serious airborne carcinogens is described. Eight lists of carcinogens were compared after eliminating chemicals not used in California, pesticides, chemicals unstable in air, or doubtful carcinogens. Further eliminations were made if production or use was under 100,000 pounds per year. The investigators included a few additional compounds. Candidate substances were ranked by additive and multiplicative algorithms and by a panel of experts. For the additive algorithm, the rating of a substance was the sum of the scores of each rating factor multiplied by a weighting factor. For the multiplicative algorithm, the substance rating equaled the product of the rating factors. The criteria rated were: 1) present use, 2) use trends, 3) emission potential, 4) stability in ambient air, 5) dispersion potential, and 6) evidence of carcinogenicity. Those compounds appearing in the top eleven of at least two lists were selected for further study. The substances selected were arsenic, asbestos, benzene, cadmium, carbon tetrachloride, chloroform, ethylene dibromide, ethylene dichloride, nitrosamines, perchloroethylene, and polychlorinated aromatic hydrocarbons. The authors found this screening approach efficient.

Michigan Department of Natural Resources
Environmental Protection Bureau, Environmental Services Division,
Critical Materials Register 1979
Lansing, Michigan
Publication No. 4833-5323 (1979)

A methodology for ranking materials hazardous to the aquatic environment is presented. The hazard assessment process considers acute toxicity, carcinogenicity, mutagenicity, teratogenicity, persistence, bioaccumulation, and other adverse effects such as subacute and chronic toxicity, embryotoxicity, phytotoxicity, and aesthetics. Chemicals are numerically scored as to their hazard, and the criteria and rationale for the scoring system are discussed. Chemicals receiving a high score are seen as posing a high environmental concern and are included in the register. Literature citations are provided for the chemicals selected to be studied. The 178 chemical substances on the 1979 register are listed. Michigan Critical Materials Registers date back to 1971. These reports are referenced in the 1979 Register, the methodologies employed are discussed, and the lists of chemicals are presented.

Nees, P.O.
Hooker Chemical Company, Niagara Falls, New York
Assessment of Oncogenic Potential - A Scoring Matrix to Determine Oncogenic Potential Proposed for Application in Risk Assessment
In: Toxic Substances Control, Vol. III - Implementing the Regulatory Program
Miller, M.L., ed., Government Institutes, Incorporated
Washington, D.C. pp. 168-82, 1979

A scoring matrix for oncogenic risk assessment that assigns weighted number values to subjective and objective results of studies is described. Positive lifetime animal studies received a primary score of 4, multiplied by metabolism, route of administration, and quality of study factors. This result is then weighted with a dose level factor and a time until tumor appearance factor. Negative results start with a minus primary score and the time weighting is correlated to survival. Epidemiology studies have a primary score of 10 multiplied by specificity of tumor type, suitability of controls, indirect association, relative risk, mixed exposure, and specificity factors, and added to a detectability of increased cancer incidence factor. The resulting adjusted primary score (AP) is weighted by adding AP times a dose response factor to AP times a consistency of association factors to AP times an exposure level factor. There is also a weighting for repetitive epidemiological studies to compensate for low confidence level in a single study. Negative studies start with a primary score of 6 and have fewer factors. For short term genetic, microbial and fluid assays individual test scores are small, positive or negative, and the only weighting factor is for supportive data. The sum of all the scores is ranked on an index of oncogenic potential that correlates the total score to an appropriate regulatory response. The author concludes that the scoring matrix can be used by people with little experience. An expert review panel would be necessary only if questions arose. The assessment could change with the results of new studies.

Pielmeier, G.R.
Tracor Jitco Inc.
Rockville, Maryland
Identification of High Risk Occupational Groups and Industrial Processes Using RTECS/NOHS Data-Final Report
Prepared for U.S. Department of Health, Education and Welfare
Public Health Service
Center for Disease Control
National Institute for Occupational Safety and Health
Division of Surveillance, Hazard Evaluations and Field Studies
Cincinnati, Ohio
Contract No. 210-78-0076, November 1979

Two NIOSH data files, the Registry of Toxic Effects of Chemical Substances and the National Occupational Hazard Survey, contain data that pertain to the risk posed to workers by toxic chemicals in the workplace. In order that occupationally and industrially defined groups of workers at high risk might be identified and given their proper priorities in NIOSH activities, algorithms were developed which (1) combine data from the two data files identified above, (2) produce indexes of the potential risk to workers in specific occupations and industries, and (3) rank the chemicals to which workers are exposed in terms of their toxicological hazard and their potential risk to all workers. The steps involved in development of these algorithms are described in this report. Five indexes are developed: Hazard Risk Index, Adjusted Hazard Risk Index, Occupational Risk Index, Industry Risk Index, and Occupation within Industry Risk Index. Typical pages from the indexes are presented.

Ross, R.H.
Oak Ridge National Laboratory
Welch, J.
U.S. Environmental Protection Agency, Office of Toxic Substances
Proceedings of the EPA Workshop on the Environmental Scoring of Chemicals
Washington, D.C., August 13-15, 1979
EPA-560/11-80-010, May 1980

The environmental scoring of chemicals is viewed by the U.S. Environmental Protection Agency as a tool to assist in the ranking or ordering of the universe of chemicals that are under the jurisdiction of the Toxic Substances Control Act. The purpose of scoring is to identify most of the chemicals that have a high probability for requiring review for regulation or testing. This report describes a three-day workshop held in Washington, D.C., August 13-15, 1979, to develop an environmental scoring system. Initial discussions centered on the determination of a safety factor (calculated as the concentration at which an effect is observed divided by environmental concentration) that would allow a numerical score to be assigned to a chemical to reflect its potential hazard. Further discussion, however, indicated that the environmental concentration of a chemical is usually not available and that the estimation of an environmental concentration is not readily accomplished; therefore, a scoring system was developed that does not require environmental concentrations. This system relates environmental exposure to toxicity by using a multiplier (3x, 2x, or 1x) which is assigned on the basis of the concentration at which an effect is observed. The applicability of the scoring system is demonstrated by scoring selected chemicals.

Stacey, G.S.; Flinn, J.E.
Battelle Columbus Labs, Ohio
Development of an Economics-Based Methodology for Projecting Future Pollution Problems
Prepared for U.S. Environmental Protection Agency
Office of Research and Development
Office of Health and Ecological Effects
Washington, D.C.
EPA-600/5-78/011, June 1978
NTIS #PB-284 337/3ST

The report describes a project designed to develop a methodology for identifying potential future toxic substance pollution problems. An approach was desired that would be systematic, comprehensive, and futuristic. The methodology developed is based on exposure and initiates the identification of problems by focusing on the potential for their occurrence in the production, exchange, and consumption of goods and services. Products are ranked according to the potential they have for being associated with future pollution problems. For the high ranked products, additional information on the chemical constitu nots of the product are identified. The final step is to analyze the chemical constituents to determine which chemicals occur frequently and in large quantities. At the same time the potential that each of the chemicals has for resulting in toxic substance problems would be assessed. In ranking the products, parameters concerning historical growth, future growth, dispersion, technical change, and value of shipments were developed and applied. A specific group of products was examined to determine their chemical content. The results of this effort showed that identifying chemical constituents of products required considerable resources. The final step of analyzing chemicals to determine frequency and quantity was developed conceptually, but due to resource limitations could not be applied.

Stanford Research Institute
Menlo Park, California
An Automated Procedure for Assessing Possible Carcinogenic Activity of Chemicals Prior to Testing
Prepared for National Cancer Institute, Bethesda, Maryland
Contracts: NO1-CP-33285 NIH-NCI-71-2045

This report discusses the systematic application of information regarding the carcinogenicity of chemicals to the prediction of carcinogenicity activity of untested chemicals. The method focuses on structural relationships between the chemicals being examined and known carcinogens. The development of an activity tree is presented for implementing a procedure for ranking chemicals prior to testing in laboratory animals. The activity tree method classifies a large number of chemicals by asking a series of increasingly more specific questions about their chemical structure. Expert consultants then offer estimates regarding the probability of any chemical in an end point of the tree being carcinogenic and the relative potency of the carcinogenic activity if the chemical proves to be carcinogenic. A level of confidence is attributed to each estimate. Estimates are also made specific to the four routes of administration (i.e., oral, inhalational, dermal, and prenatal) of the compound to the test animal, corresponding to the routes used in the exposure estimates. For the development of this activity tree, six experts offered their considerations on five classes of substances known to contain carcinogens: naturally occurring substances, aliphatic nitrogen-containing compounds, polycyclic aromatic hydrocarbons, aromatic amines, and inorganic compounds. Their reports are summarized and the current activity values for the tree are given. An appendix describes computer implementation of the activity methodology.

Stanford Research Institute
Menlo Park, California
Criteria and Procedures for Chemical Selection
Prepared for Chemical Selection Working Group, National Cancer Institute, Bethesda, Maryland
Contract: NO1-CP-95607
October, 1977

This report describes the criteria and procedures used by the Chemical Selection Working Group to select chemicals for NCI's carcinogenesis bioassay program. Chemicals are nominated for consideration by a variety of government agencies and others. A two-step process is then used for selection. The first-step involves gathering limited data to determine if the chemical meets qualifying criteria. In order to qualify, a chemical must: (1) not currently be undergoing testing by the NCI bioassay program or other programs; (2) not have been adequately tested previously; and (3) have high annual consumption or evidence of exposure from environmental occurrence. If the chemical meets these criteria more extensive selection criteria are then applied. This step involves analyses of: 1) exposure information including consumption, use patterns, human exposure, and environmental occurrence; and 2) evidence for possible carcinogenic activity including human data, animal data, short-term tests, metabolism, and structural/activity relationships.

Stephenson, M.E.
National Science Foundation, Washington, D.C.
An Approach to the Identification of Organic Compounds Hazardous to the Environmental and Human Health
Ecotoxicology and Environmental Safety, 1:39-48 (1977)

Results are presented from a workshop ranking hazardous chemicals and identifying key problem areas for future research. Eighty organic compounds were ranked according to their environmental impact and their hazard to human health. A scatter plot of the 80 compounds indicating their relative ranking in terms of both criteria showed that 10 organohalides require immediate study. Major impact or problem areas around which future research could be organized include: 1) natural sources of organic compounds; 2) contribution to biochemical and geochemical pools; 3) effects of transport and translocation of toxic elements and micronutrients; 4) toxic degradation products and formation of secondary pollutants; 5) remote effects; 6) persistence in the absence of other effects; and 7) bioaccumulation. It is also recommended that the environmental impact and human health hazard of the carbon chlorine bond be studied. Production figures and estimated annual release rates for the 80 compounds are given.

TSCA Interagency Testing Committee: Initial Report to the Administrator, Environmental Protection Agency
42 FR 197:55025-80, October 12, 1977

Section 4(e) of the Toxic Substances Control Act (TSCA) requires the establishment of a committee to identify and recommend to the EPA Administrator chemical substances which should be tested to determine their hazard to human health or the environment. This report documents procedures used by the TSCA-Interagency Testing Committee for selecting those chemical substances recommended for testing. Reasons for each recommendation are outlined. Available data and potential for carcinogenic, mutagenic, teratogenic, and chronic toxic effects were all considered, as was the ability of the substances to bioaccumulate or cause deleterious environmental effects. A scoring system which took into account both available information and the lack of it for these factors was used in the screening process. Categories or substances recommended for further testing include alkyl paraffins, chloromethane, cresols, hexachloro-1,3-butadiene, nitrobenzene, toluene, and the xylenes. The formation of the Interagency Testing Committee, its responsibilities, and the approach used in forming the recommendations are discussed. Sources of data used in the preparation of the initial substances list are listed. A linear weighting scheme used to rank the substances is discussed.

United Nations Environmental Programme
Initial Report on the Priority Pollutants Project
Nairobi, October 1978

Results are presented from the initial phase of the priority pollutants project. The objectives include: (1) compiling a list of hazardous chemicals which have been given priority consideration by governments and other organizations, (2) proposing a systematic process for selecting priority pollutants with emphasis given to the needs of developing countries, and (3) identifying several lists of chemicals or categories for further UNEP attention. Section 2 includes a compilation of approximately 230 selected substances of concern to various national and international institutions. Section 3 discusses the general problems associated with identifying and ranking environmental hazards. It includes a discussion of the distinguishing features between developed and developing areas which give rise to different sets of priorities for environmental pollution. This section concludes by outlining the selection criteria to be used in a ranking system for both developed and developing areas. Criteria include exposure, carcinogenicity, mutagenicity, teratogenicity, acute toxicity, other health effects, the influence of nutrition and infectious disease on toxicity, persistence and bioaccumulation, and environmental agents. The method uses expert opinion, information on structure activity relationships, and production and environmental exposure data in a multistage screening process where a relatively large number of substances are considered initially. In subsequent steps a smaller subset is selected for collection of more data and more thorough review. Section 5 suggests several categories of hazardous pollutants which may be of interest to the United Nations Environment Program. For each area an interim list of priority pollutants is proposed.

Van Netten, C.
Simon Fraser University, Burnaby, British Columbia, Canada
Critical Review of Strategies Aimed at Identifying Chemicals Hazardous to Human Health and the Environment
Prepared for Department of National Health and Welfare, Ottawa, Canada, March 8, 1978

Criteria are presented for evaluating the effectiveness of existing chemical screening strategies. Environmental criteria include production and release, distribution in the atmosphere, degradation, bioaccumulation, toxicity, as well as synergistic and antagonistic effects within the environment. Human health criteria include exposure of the total population or specific groups, distribution of the substance within the body, accumulation and excretion, general toxicity, mutagenicity, teratogenicity, carcinogenicity, and possible synergistic and antagonistic effects in humans. Decision making criteria are used to evaluate whether the recommendations made by the different screening procedures allow easy access to information so that specific decisions can be made. Six screening methods are then assessed by these criteria. The author suggests that an optimum combination of these methods could be derived which would reject a maximum number of chemicals at a minimum cost.

Venezian, E.C.
Arthur D. Little, Inc.
Cambridge, Massachusetts
Pre-screening for Environmental Hazards - A System for Selecting and Prioritizing Chemicals
Prepared for U.S. Environmental Protection Agency
Office of Toxic Substances
Washington, D.C.
EPA/560/1-77/00Z, April 1977

Alternatives were considered for pre-screening chemicals for their potential to cause environmental hazards. A system design concept which takes into account both the toxicity of the chemical and the eventual levels which it can be expected to reach in the environment was selected for further analysis. It is noted that, although neither toxicity nor eventual levels can be predicted with great accuracy, the accuracy attainable by simple methods appears adequate for selecting and ranking chemicals for additional investigation. A specific design which relies on data which are usually available was developed to the point of testing the feasibility of collecting the necessary data and performing the required computations on five chemicals.